

from records by processor check or otherwise, the commercial processor of that low-acid food shall either fully reprocess that portion of the production involved, keeping full records of the reprocessing conditions or, alternatively, must set aside that portion of the product involved for further evaluation as to any potential public health significance. Such evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless this evaluation demonstrates that the product had been given a thermal process that rendered it free of microorganisms of potential public health significance, the product set aside shall be either fully reprocessed to render it commercially sterile or destroyed. A record shall be made of the evaluation procedures used and the results. Either upon completion of full reprocessing and the attainment of commercial sterility or after the determination that no significant potential for public health hazard exists, that portion of the product involved may be shipped in normal distribution. Otherwise, the portion of the product involved shall be destroyed. All process deviations involving a failure to satisfy the minimum requirements of the scheduled process, including emergencies arising from a jam or breakdown of a continuous agitating retort necessitating cooling the retort for repairs, shall be recorded and made the subject of a separate file (or a log identifying the appropriate data) detailing those deviations and the actions taken.

Subpart F—Records and Reports

§ 113.100 Processing and production records.

(a) Processing and production information shall be entered at the time it is observed by the retort or processing system operator, or other designated person, on forms that include the product, the code number, the date, the retort or processing system number, the size of container, the approximate number of containers per coding interval, the initial temperature, the actual processing time, the temperature-indicating device and temperature-recording device readings, and other appropriate processing data. Closing machine vacuum in vacuum-packed products, maximum fill-in or drained weight, or other critical factors specified in the scheduled process shall also be recorded. In addition, the following records shall be maintained:

(1) *Still retorts.* Time steam on; time temperature up to processing temperature; time steam off; venting time and temperature to which vented.

(2) *Agitating retorts.* Functioning of condensate bleeder; retort speed; and, when specified in the scheduled process, headspace, consistency, maximum drained weight, minimum net weight, and percent solids.

(3) *Hydrostatic retorts.* The temperature in the steam chamber between the steam-water interface and the lowest container position; speed of the container conveyor chain; and, when the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, the temperatures near the top and the bottom of each hydrostatic water leg.

(4) *Aseptic processing and packaging systems.* Product temperature in the holding tube outlet as indicated by the temperature-indicating device and the temperature-recording device; differential pressure as indicated by the differential pressure recorder-controller, if a product-to-product regenerator is used; product flow rate, as determined by the flow controlling device or by filling and closing rates; sterilization media flow rate or temperature or both; retention time of containers, and closures when applicable, in the sterilizing environment; and, when a batch system is used for container and/or closure sterilization, sterilization cycle times and temperatures.

(5) *Flame sterilizers.* Container conveyor speed; surface temperature at the beginning and at the end of the holding period; nature of container.

(6) *Food preservation methods wherein critical factors such as water activity are used in conjunction with thermal processing.* Product formulation and scheduled processes used, including the thermal process, its associated critical factors, as well as other critical factors, and results of a_w determinations.

(7) *Other systems.* Critical factors specified in the formulation of the product or in the scheduled process.

(b) Temperature-recording device records shall be identified by date, retort number, and other data as necessary, so they can be correlated with the record of lots processed. Each entry on the processing and production records shall be made by the retort or processing system operator, or other designated person, at the time the specific retort or processing system condition or operation occurs, and this retort or processing system operator or other designated person shall sign or initial each record form. Not later than 1 working day after the actual process, and before shipment or release for distribution, a representative of plant management who is qualified by suitable training or experience shall review all processing and production records for completeness and to ensure that the product received the scheduled process. The records, including temperature-recording device records, shall be signed or initialed and dated by the reviewer.

(c) Records of the accuracy of a temperature-indicating device shall include:

(1) A reference to the tag, seal, or other means of identity used by the processor to identify the temperature-indicating device;

(2) The name of the manufacturer of the temperature-indicating device;

(3) The identity of the reference device, equipment, and procedures used for the accuracy test and to adjust the temperature-indicating device or, if an outside facility is used to conduct the accuracy test for the temperature-indicating device, a guarantee, certificate of accuracy, certificate of calibration, or other document from the facility that includes a statement or other documentation regarding the traceability of the accuracy to a National Institute of Standards and Technology (NIST) or other national metrology institute standard;

(4) The identity of the person or facility that performed the accuracy test and adjusted or calibrated the temperature-indicating device;

(5) The date and results of each accuracy test, including the amount of calibration adjustment; and

(6) The date on or before which the next accuracy test must be performed.

(d) Records of the accuracy of a reference device maintained by the processor shall include:

(1) A reference to the tag, seal, or other means of identity used by the processor to identify the reference device;

(2) The name of the manufacturer of the reference device;

(3) The identity of the equipment and reference to procedures used for the accuracy test and to adjust or calibrate the reference device or, if an outside facility is used to conduct the accuracy test for the reference device, a guarantee, certificate of accuracy, certificate of calibration, or other document from the facility that includes a statement or other documentation regarding the traceability of the accuracy to a NIST or other national metrology institute standard;

(4) The identity of the person or facility that performed the accuracy test and adjusted or calibrated the reference device;

(5) The date and results of each accuracy test, including the amount of calibration adjustment; and

(6) The date on or before which the next accuracy test must be performed.

(e) Records of all container closure examinations shall specify the product code, the date and time of container closure inspections, the measurements obtained, and all corrective actions taken. Records shall be signed or initialed by the container closure inspector and reviewed by management with sufficient frequency to ensure that the containers are hermetically sealed. The records shall be signed or initialed and dated by the reviewer.

(f) Records shall be maintained to identify the initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise rendered unfit for their intended use.

(g) Copies of all records provided for in this part, except those required under §113.83 establishing scheduled

processes, shall be retained at the processing plant for a period of not less than 1 year from the date of manufacture, and at the processing plant or other reasonably accessible location for an additional 2 years. If, during the first year of the 3-year record-retention period, the processing plant is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack.

(h) Records of this part may be maintained electronically, provided they are in compliance with part 11 of this chapter.

[44 FR 16215, Mar. 16, 1979, as amended at 76 FR 11923, Mar. 3, 2011]

PART 114—ACIDIFIED FOODS

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Subpart F—Records and Reports

114.100 Records.

AUTHORITY: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

SOURCE: 44 FR 16235, Mar. 16, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 114.3 Definitions.

For the purposes of this part, the following definitions apply.

(a) *Acid foods* means foods that have a natural pH of 4.6 or below.

(b) *Acidified foods* means low-acid foods to which acid(s) or acid food(s) are added; these foods include, but are not limited to, beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish,

singly or in any combination. They have a water activity (a_w) greater than 0.85 and have a finished equilibrium pH of 4.6 or below. These foods may be called, or may purport to be, “pickles” or “pickled _____.” Carbonated beverages, jams, jellies, preserves, acid foods (including such foods as standardized and nonstandardized food dressings and condiment sauces) that contain small amounts of low-acid food(s) and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food, and foods that are stored, distributed, and retailed under refrigeration are excluded from the coverage of this part.

(c) *Lot* means the product produced during a period indicated by a specific code.

(d) *Low-acid foods* means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (a_w) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

(e) *Scheduled process* means the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority.

(f) *Shall* is used to state mandatory requirements.

(g) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(h) *Water activity* (a_w) is a measure of the free moisture in a product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

[44 FR 16235, Mar. 16, 1979, as amended at 61 FR 14245, Apr. 1, 1996]

§ 114.5 Current good manufacturing practice.

The criteria in §§ 114.10, 114.80, 114.83, 114.89, and 114.100, as well as the criteria in part 110 of this chapter, apply